

clinical diagnostic laboratory test (CDLT).

[81 FR 41098, June 23, 2016]

§ 414.502 Definitions.

For purposes of this subpart—

Actual list charge means the publicly available rate on the first day the new advanced diagnostic laboratory test (ADLT) is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date.

Advanced diagnostic laboratory test (ADLT) means a clinical diagnostic laboratory test (CDLT) covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the single laboratory that designed the test or a successor owner of that laboratory, and meets one of the following criteria:

(1) The test—

(i) Is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins;

(ii) When combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies);

(iii) Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and

(iv) May include other assays.

(2) The test is cleared or approved by the Food and Drug Administration.

Applicable information, with respect to each CDLT for a data collection period:

(1) Means—

(i) Each private payor rate for which final payment has been made during the data collection period;

(ii) The associated volume of tests performed corresponding to each private payor rate; and

(iii) The specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test.

(2) Does not include information about a test for which payment is made on a capitated basis.

Applicable laboratory means an entity that:

(1) Is a laboratory, as defined in § 493.2 of this chapter;

(2) Bills Medicare Part B under its own National Provider Identifier (NPI);

(3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, Medicare Advantage payments under Medicare Part C, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period from one or a combination of the following sources:

(i) This subpart G.

(ii) Subpart B of this part.

(4) Receives at least \$12,500 of its Medicare revenues from this subpart G. Except, for a single laboratory that offers and furnishes an ADLT, this \$12,500 threshold—

(i) Does not apply with respect to the ADLTs it offers and furnishes; and

(ii) Applies with respect to all the other CDLTs it furnishes.

Data collection period is the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period.

Data reporting period is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period.

National Provider Identifier (NPI) means the standard unique health identifier used by health care providers for billing payors, assigned by the National Plan and Provider Enumeration System (NPPES) in 45 CFR part 162.

New advanced diagnostic laboratory test (ADLT) means an ADLT for which payment has not been made under the clinical laboratory fee schedule prior to January 1, 2018.

New ADLT initial period means a period of 3 calendar quarters that begins on the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage determination is made or ADLT status is granted by CMS.

New clinical diagnostic laboratory test (CDLT) means a CDLT that is assigned a new or substantially revised

§ 414.504

42 CFR Ch. IV (10–1–16 Edition)

Healthcare Common Procedure Coding System (HCPCS) code, and that does not meet the definition of an ADLT.

New test means any clinical diagnostic laboratory test for which a new or substantially revised Healthcare Common Procedure Coding System Code is assigned on or after January 1, 2005.

Private payor means:

(1) A health insurance issuer, as defined in section 2791(b)(2) of the Public Health Service Act.

(2) A group health plan, as defined in section 2791(a)(1) of the Public Health Service Act.

(3) A Medicare Advantage plan under Medicare Part C, as defined in section 1859(b)(1) of the Act.

(4) A Medicaid managed care organization, as defined in section 1903(m)(1)(A) of the Act.

Private payor rate, with respect to applicable information:

(1) Is the final amount that is paid by a private payor for a CDLT after all private payor price concessions are applied and does not include price concessions applied by a laboratory.

(2) Includes any patient cost sharing amounts, if applicable.

(3) Does not include information about denied payments.

Publicly available rate means the lowest amount charged for an ADLT that is readily accessible in such forums as a company Web site, test registry, or price listing, to anyone seeking to know how much a patient who does not have the benefit of a negotiated rate would pay for the test.

Reporting entity is the entity that reports tax-related information to the Internal Revenue Service (IRS) using its Taxpayer Identification Number (TIN) for its components that are applicable laboratories.

Single laboratory, for purposes of an ADLT, means:

(1) The laboratory, as defined in 42 CFR 493.2, which furnishes the test, and that may also design, offer, or sell the test; and

(2) The following entities, which may design, offer, or sell the test:

(i) The entity that owns the laboratory.

(ii) The entity that is owned by the laboratory.

Specific HCPCS code means a HCPCS code that does not include an unlisted CPT code, as established by the American Medical Association, or a Not Otherwise Classified (NOC) code, as established by the CMS HCPCS Workgroup.

Substantially Revised Healthcare Common Procedure Coding System Code means a code for which there has been a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte specific test).

Successor owner, for purposes of an ADLT, means a single laboratory, that has assumed ownership of the single laboratory that designed the test or of the single laboratory that is a successor owner to the single laboratory that designed the test, through any of the following circumstances:

(1) *Partnership*. The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law.

(2) *Unincorporated sole proprietorship*. Transfer of title and property to another party.

(3) *Corporation*. The merger of the single laboratory corporation into another corporation, or the consolidation of two or more corporations, including the single laboratory, resulting in the creation of a new corporation. Transfer of corporate stock or the merger of another corporation into the single laboratory corporation does not constitute change of ownership.

Taxpayer Identification Number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the IRS in 26 CFR 301.6109–1.

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§ 414.504 Data reporting requirements.

(a) In a data reporting period, a reporting entity must report applicable information for each CDLT furnished by its component applicable laboratories during the corresponding data collection period, as follows—

(1) For CDLTs that are not ADLTs, every 3 years beginning January 1, 2017.